



Exactech[®], Inc
Thomas McNamara
Senior Regulatory Specialist
2320 NW 66th Court
Gainesville, Florida 32653

March 9, 2018

Re: K173388

Trade/Device Name: Exactech[®] Equinox[®] Stemless Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: February 6, 2018
Received: February 7, 2018

Dear Thomas McNamara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173388

Device Name

Exactech® Equinox® Stemless Shoulder

Indications for Use (Describe)

The Equinox Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total shoulder arthroplasty are as follows:

- Osteoarthritis, osteonecrosis or post-traumatic degenerative problems
- Congenital abnormalities in the skeletally mature
- Primary and secondary necrosis of the humeral head.
- Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
- To restore mobility from previous procedures (e.g. previous fusion)

The Equinox Stemless Shoulder humeral components are indicated for press-fit, uncemented use.

The Equinox Stemless Shoulder System is intended to be used with the cemented Equinox glenoid components.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**Exactech® Equinox® Stemless Shoulder
Traditional 510(k) – 510(k) Summary**

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: February 6, 2018

Contact Person: Thomas McNamara, RAC
Senior Regulatory Specialist

Phone: (352) 377-1140
Fax: (352) 378-2617

Proprietary Name: Exactech® Equinox® Stemless Shoulder

Common Name: Shoulder Prosthesis

Classification Name: Prosthesis, Total Anatomic Shoulder, Uncemented
Metaphyseal Humeral Stem with No Diaphyseal Incursion,
Semi-Constrained, 21 CFR 888.3660, Class II, Product
Code PKC

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Tornier Simpliciti Shoulder System (K143552)
- Exactech Humeral Heads (K042021, K140063)

Reference Devices

- Exactech Equinox Resurfacing Humeral Head System (K131298)
- Exactech Novation® Crown Cup® with InteGrip™ Acetabular Shell, Cluster-Hole (K102975)
- Exactech Optetrak Logic® Metaphyseal Cones (K153595)

Device Description

The Equinox Stemless Shoulder is intended to be used with Exactech glenoid components for use in Total Shoulder Arthroplasty. The Exactech glenoid components are indicated for cemented use. The Equinox Stemless Shoulder includes humeral components and humeral heads. The proposed Equinox Stemless Humeral Components are additively manufactured from Ti-6Al-4V, and have porous regions. The Equinox Stemless Humeral Heads are manufactured from Cobalt Chrome. The Equinox Stemless Humeral Components are available in two types, Caged and Non-Caged, with each type available in three sizes, with lengths between 17mm and 24mm. The Equinox Stemless Humeral Heads are available in 12 sizes, with diameters between 38mm and 53mm and two height options (Extra Short, Short).

Exactech® Equinox® Stemless Shoulder Traditional 510(k) – 510(k) Summary

Indications for Use

The Equinox Stemless Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint where anatomic total shoulder arthroplasty is determined by the surgeon to be the preferred method of treatment.

Clinical indications for anatomic total shoulder arthroplasty are as follows:

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- To restore mobility from previous procedures (e.g. previous fusion)

The Equinox Stemless Shoulder humeral components are indicated for press-fit, uncemented use.

The Equinox Stemless Shoulder System is intended to be used with the cemented Equinox glenoid components.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices have similar indications for use.
- **Materials/Surface Finish/Coatings.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices are composed of the same or similar biocompatible substrate materials, and the same or similar surface finish for permanent implants.
- **Design Features.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices have similar design features.
- **Dimensions.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices are dimensionally comparable.
- **Sterilization.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices are provided sterile for single use only.
- **Performance Requirements.** The proposed Exactech Equinox Stemless Shoulder components and the predicate devices conform to recognized performance standards for total shoulder replacement devices.

**Exactech® Equinox® Stemless Shoulder
Traditional 510(k) – 510(k) Summary**

Non-Clinical Testing

The following engineering analyses were performed to demonstrate that the Exactech Equinox Stemless Shoulder perform as intended and are substantially equivalent to the identified predicate devices:

- Fatigue Testing
- Axial Pull Out Testing
- Torque out Testing
- Taper Disengagement Testing

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Equinox Stemless Shoulder components meet recommended limits per FDA's *Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile*.

Substantial Equivalence Conclusion

Based on consideration of indications for use, technological characteristics, and results of non-clinical testing, it was concluded that the Exactech Equinox Stemless Shoulder demonstrates substantial equivalence to the referenced predicate devices.